Department of Defense

INSTRUCTION

NUMBER 6480.4

August 5, 1996

ASD(HA)

SUBJECT: Armed Services Blood Program (ASBP) Operational Procedures

References: (a) DoD Directive 6000.12, "Health Services Operations and Readiness," April 29, 1996
(b) DoD Instruction 6480.4, "DoD Blood Program - Mobilization Planning Factors," March 19, 1982 (hereby canceled)
(c) Title 21, Code of Federal Regulations (CFR), Parts 200 to 299, 600 to 799, and 800-899, current edition
(d) Executive Order 12656, "Assignment of Emergency Preparedness Responsibilities," November 18, 1988
(e) through (i), see enclosure 1

1. REISSUANCE AND PURPOSE

This Instruction:

1.1. Implements policy, assigns responsibilities, and prescribes procedures under reference (a) to carry on the responsibilities of the ASBP during peacetime, contingency, and wartime operations.

1.2. Reissues reference (b) and prescribes the standard terminology and planning factors in enclosure 3 for use in computing mobilization requirements for the blood products (BPs) needed for the treatment of conventional wartime casualitites. Those factors do not include electrolytes, colloids, or fluid requirements.

1.3. Establishes the requirement for publishing and/or procurement and utilization by military blood bank (BB) facilities of the American Association of Blood Banks (AABB) Standards (Army FM 8-70; NAVMED P-5120; AFM 41-111; "Standards for Blood Banks and Transfusion Services," AABB, current edition), the AABB

"Technical Manual of the AABB", current edition), and the "Accreditation Requirements Manual," current edititon, AABB.

1.4. Establishes the requirement for procurement and use by military BB elements of the CFR (reference (c)), and implementation of BB procedures, as appropriate.

1.5. Defines the responsibilities of the Secretary of the Army as the DoD Executive Agent for the ASBP Office (ASBPO), and defines review and guidance responsibilities of the Chairman of the Joint Chiefs of Staff.

1.6. Defines the responsibilities of the Secretary of the Air Force as the DoD Executive Agent for the Armed Services Whole Blood Processing Laboratories (ASWBPL) and the blood transshipment centers (BTCs) and/or transportable BTCs (TBTCs).

2. APPLICABILITY AND SCOPE

This Instruction:

2.1. Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Unified Combatant Commands, the Defense Agencies, and the DoD Field Activities (hereafter referred to as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

2.2. Applies to the Federal and civilian agencies collecting blood on military installations.

2.3. Defines the scope of the DoD ASBP and encompasses the blood program of the DoD organizations listed in subsection 2.1., above, and the ASBPO. It includes the following:

2.3.1. The collection, processing, distribution and use of blood and its components by military facilities on a local or regional basis according to the policies of the respective Military Departments.

2.3.2. The procurement of blood and its components, for military use, from sources outside the Department of Defense.

2.4. Applies to the maintenance and implementation by the Assistant Secretary of

Defense for Health Affairs (ASD(HA)), the ASBPO, the Military Departments, and the Unified Combatant Commands, of plans to provide for the activities in paragraphs 2.3.1. and 2.3.2., above.

2.5. Applies to a research and development program devoted to progress and improvement in the areas of blood derivatives, plasma volume expanders, blood substitutes and the techniques, facilities, and materiel related thereto.

3. DEFINITIONS

Terms used in this Instruction are defined in enclosure 2.

4. POLICY

It is DoD policy under reference (a) that the ASBP shall be a single, integrated blood products system composed of the Military Services' and the Unified Combatant Commands' blood programs. This program provides, to the maximum extent possible, all blood and blood products to DoD medical treatment facilities (MTFs) for both peacetime and wartime. That program adheres to the good manufacturing practices and regulations of the Food and Drug Administration (FDA), and the AABB Standards. The readiness posture of the program is maintained through an active voluntary donor program; a comprehensive blood training program at all personnel levels; a dedicated blood research and development program; and aggressive involvement in joint exercises.

5. RESPONSIBILITIES

5.1. The Assistant Secretary of Defense for Health Affairs, under the Under Secretary of Defense for Personnel and Readiness shall:

5.1.1. Develop military blood program policies, in accordance with E.O. 12656 (reference (d)).

5.1.2. Ensure that blood program requirements are appropriately reflected in the Defense Medical Programming Guidance and in the DoD budget.

5.1.3. Co-Chair with Director, Defense Research and Engineering, the Armed Services Biomedical Research, Evaluation and Management (ASBREM) committee, ensuring the development of research requirements relating to BPs which

includes:

5.1.3.1. Facilitate the coordination of the Joint Technical Coordinating Group, Combat Casualty Care, of the ASBREM with ASBPO to ensure that the development of blood research is in concert with Unified Combatant Command requirements.

5.1.3.2. Issue policy guidance on BPs related to the ASBP.

5.1.4. Provide policy guidance on planning and resource oversight of initiatives designed to implement automated data processing support to all ASBP elements.

5.1.5. Provide policy guidance on allowing civilian blood agencies collecting blood on military installations and/or contracted facilities and/or ships to minimize impacting on the military blood program in meeting its readiness requirements.

5.1.6. Provide policy guidance on allowing non-DoD civilians on military installations and/or contract facilities and/or ships, during a state of war or a major catastrophic event, to provide blood donations.

5.1.7. Coordinate the selection process of the Director, ASBPO, by agreement among the Surgeons' General of the Army, the Navy, the Air Force, and appoint, in writing, the selectee, who will normally serve a 4-year tour. The other staff officers of the ASBPO shall be designated as "deputy directors." The directorship shall normally rotate sequentially among the Services.

5.2. The Chairman of the Joint Chiefs of Staff shall:

5.2.1. Review and provide guidance on all matters of blood support in joint operations both for planning and execution, in accordance with the Chairman of the Joint Chiefs of Staff memo-randum (reference (e)).

5.2.2. Coordinate with and advise the OSD, on behalf of the Unified Combatant Commanders, to activate the ASBP for contingency blood support.

5.2.3. The Commanders of the Unified Combatant Commands shall:

5.2.3.1. Ensure that their respective component commands establish and maintain integrated blood programs for providing BPs to the medical elements within their area of responsibility.

5.2.3.2. Ensure that ASD(HA) blood program policies are followed and joint doctrine is used as written in Joint Pub 4-02 (reference (f)).

5.2.3.3. Appoint a Joint Blood Program Officer (JBPO), authorized to coordinate with the ASBPO and manage the theater's blood program for the Unified Combatant Commander. That officer ensures that BPs and blood services medical readiness requirements are identified and that DoD capabilities are adequate to meet those requirements.

5.4. The Secretaries of the Military Departments shall:

5.4.1. Establish and maintain a blood program that provides blood and BPs, to the maximum extent possible, to component MTFs in peacetime and wartime, in accordance with 21 CFR (reference (c)).

5.4.2. Provide funds, facilities, a student officer contingent, and support personnel, as required, to maintain the Tri-Service Blood Bank Fellowship Program, the Armed Services blood donor centers (BDCs), the ASWBPLs, the blood product depots (BPDs), and the ASBPO.

5.4.3. Fund transportation of respective Service-collected and processed blood and BPs and incidental expenses associated with their delivery to the first Continental United States (CONUS) destination.

5.5. The Secretary of the Army shall:

5.5.1. Provide, as the DoD Executive Agent for ASBPO, support personnel, facilities, and budgetary resources, as required.

5.5.2. Provide funds for all blood and BPs purchased through activation of standby civilian contracts for blood and BPs.

5.5.3. Provide appropriate support personnel, facilities, budgetary resources, as required to support dedicated Army BPDs designated by and in the Unified Combatant Commands in an active status that are capable of activation and functional operation, as required in the respective campaign plans or as required by the ASBPO.

5.5.4. Exercise the Army BPDs, as requested by the ASBPO, in coordination with the appropriate Unified Combatant Command.

5.5.5. Coordinate with the Chairman of the Joint Chiefs of Staff, and the ASBPO, before closing, transferring, or deactivating an Army BPD operating in accordance with this Instruction.

5.5.6. Provide personnel for the ASWBPLs, in accordance with staffing requirements explained in the reference noted in paragraph 5.6.5.,below.

5.5.7. Ensure Army BDCs meet or exceed the ASBPO assigned monthly BPs quotas and provide those BPs to the ASWBPLs on a weekly scheduled basis according to the Service Blood Program Officer (SBPO).

5.5.8. In addition to maintaining Blood Platoons in an operational status, have them participate in exercises as blood supply units, as requested by the ASBPO, and the Unified Combatant Commands.

5.6. The Secretary of the Air Force shall:

5.6.1. Provide, as the DoD Executive Agent for ASWBPLs, BTCs, and TBTCs, appropriate support personnel, facilities, and budgetary resources, as required.

5.6.2. Maintain at least two ASWBPLs in active status and at appropriate CONUS air terminals to process and ship BPs to CONUS and outside CONUS (OCONUS) locations in support of Unified Combatant Command requirements, in coordination with the Chairman of the Joint Chiefs of Staff.

5.6.3. Have the ASWBPLs, BTCs, and/or TBTCs participate in exercises, as requested by the ASBPO, and in coordination with the appropriate Unified Combatant Command.

5.6.4. Coordinate with the Chairman of the Joint Chiefs of Staff and the ASBPO, before closing, transferring, or deactivating an ASWBPL that is operating in accordance with this Instruction.

5.6.5. Coordinate the joint staffing of the designated ASWBPLs by appropriate medical personnel of the Army, the Navy, and the Air Force, in accordance with staffing criteria outlined in TM 8-227-11/NAVMED P-5123/AFI 44-118, "Operational Procedures for the Armed Services Blood Program Elements," September 1, 1995.

5.6.6. Obtain concurrence of the respective Commander in Chief (CINC) or

his and/or her designated representative before closing, deactivating, or transferring a BTC and/or a TBTC.

5.6.7. Ensure Air Force BDCs meet or exceed the ASBPO-assigned monthly BPs quotas and provide those BPs to the ASWBPLs on a weekly scheduled basis according to the SBPO.

5.7. The Secretary of the Navy shall:

5.7.1. Provide appropriate support personnel, facilities, budgetary resources, as required to support dedicated Navy BPDs designated by and in the Unified Combatant Commands in an active status that are capable of activation and functional operation as required in the respective campaign plans or as required by the ASBPO.

5.7.2. Exercise the Navy BPDs, as requested by the ASBPO, in coordination with the appropriate Unified Combatant Command.

5.7.3. Coordinate with the Chairman of the Joint Chiefs of Staff and the ASBPO, before closing, transferring, or deactivating a Navy BPD that is operating in accordance with this Instruction.

5.7.4. Provide personnel for the ASWBPLs, in accordance with staffing requirements explained in the reference noted in paragraph 5.6.5., above.

5.7.5. Ensure Navy BDCs meet or exceed the ASBPO assigned monthly BPs quotas and provide those BPs to the ASWBPLs on a weekly scheduled basis according to the SBPO.

5.8. The Commander in Chief, U.S. Transportation Command, shall:

5.8.1. Coordinate with ASBPO in the development of plans to transport blood and BPs from CONUS BDCs to ASWBPLs.

5.8.2. Coordinate transportation of blood and BPs from ASWBPLs to the Unified Combatant Command's designated "aerial port of debarkation."

6. PROCEDURES

6.1. The Director, ASBPO, shall:

6.1.1. Coordinate the day-to-day activities of the ASBP, in accordance with

the policies established by the ASD(HA) and the plans, programs, standards, and procedures established by the Department of Defense, the Chairman of the Joint Chiefs of Staff, the Unified Combatant Commands, and the Military Services. As required, serve as the DoD direct liaison for coordination and policy recommendations with all of the organizations in subparagraphs 6.1.1.1. through 6.1.1.4., below. The ASBPO serves as the single military point of contact for BB matters for other Government and civilian agencies having an interest in BPs and related items. That includes, but is not limited to, the Unified Combatant Commands and the following Federal Agencies:

6.1.1.1. The FDA Center for Biologics and Research (CBER).

6.1.1.2. The Department of Health and Human Services Office of Emergency Preparedness and/or National Disaster Medical System, and the Blood Safety Committee.

6.1.1.3. The Defense Logistics Agency for activation of the contingency blood contracts, blood equipment and supply procurement contracts.

6.1.1.4. The Defense Medical Standardization Board on the development of essential characteristics of equipment, supplies, policies, and procedures associated with military blood banking.

6.1.2. Direct the ASBPO, which shall be staffed by a minimum of three Medical Service Corps (Army, Navy) and/or Biomedical Sciences Corps (Air Force) officers in the grade of 0-4, or above. One of the officers shall serve as the Director, and the others as Deputy Directors. All ASBPO members carry out their ASBPO assignments as their primary duty.

6.1.3. Receive and take appropriate action on military requirements for BPs that exceed Military Service resources.

6.1.4. Coordinate the preparation of written guidelines for blood banking policies to be used as minimum standards by the Military Services.

6.1.5. Coordinate the development of technical aspects of blood research programs, conveying requirements through ASD(HA) to the ASBREM.

6.1.6. Collate net DoD emergency and mobilization BP requirements, and ensure that plans are in place to meet those requirements.

6.1.7. Establish contingency BP quotas to be maintained at the ASWBPL(s),

and assign requirements to the Military Services to meet those quotas.

6.1.8. In coordination with the Chairman of the Joint Chiefs of Staff, oversee the operations of the ASBP during contingencies.

6.1.9. Coordinate the theater blood program issues with the CINCs through the Chairman of the Joint Chiefs of Staff. That includes the following:

6.1.9.1. Operations Plan and Contingency Plan blood support review, to include sourcing of blood requirements.

6.1.9.2. Pre-positioning of frozen BPs to meet contingency theater BP requirements.

6.1.9.3. Direct liaison with allied blood programs for contingency blood support requirements.

6.1.10. Maintain a lookback program, as established in the ASD(HA) Memorandum (reference (g)), to be able to inform former blood recipients or donors that they may have received or donated infected blood or BPs. Appropriate counselling, testing, and treatment should be provided.

6.2. The Directors, ASWBPL, shall:

6.2.1. Direct the day-to-day operations of the ASWBPL to ensure that the facility, personnel, equipment, and supplies shall support both peacetime and contingency requirements.

6.2.2. Receive BDC products to maintain a contingency stockpile and act as a central shipping point for forwarding those BPs to operational units.

6.2.3. Provide a technical review point for donor center products before their shipment to operational units.

6.2.4. Provide, through a rotational basis, blood support for CONUS and OCONUS MTFs, as directed, during noncontingency periods, while maintaining the ASBPO-required contingency inventory.

6.2.5. Provide support to exercises (real-world blood support and simulated blood), as directed by the ASBPO.

7. INFORMATION REQUIREMENTS

7.1. Forms Requirements. The following forms shall be standardized and used in the ASBP:

7.1.1. DD 572, "Blood Donation Record."

7.1.2. DD 573, "A Shipping Inventory of Blood Products."

7.1.3. DD Form 2555, "ASBP Blood Bank Operational Report."

7.1.4. SF 518, "Blood or Blood Component Transfusion."

7.2. ASBP Blood Reports. Reports using the forms listed in paragraphs 7.1.1. through 7.1.4., above, shall be completed and submitted to the appropriate authority, as follows:

7.2.1. Peacetime Reports. DD Form 2555 is the standardized report to report routine blood program operations to the ASBPO. The SBPOs shall submit BB operational reports to the ASBPO using DD Form 2555. The JBPOs may provide informational ad hoc operational reports. Those reports shall be submitted each calendar quarter to the ASBPO within 45 days of the end of a quarter. This information requirement has been assigned Report Control Symbol DD-HA(Q)1831 in accordance with DoD 8910.1-M (reference (h)). The reporting requirements identified at 7.1.1., 7.1.2., 7.1.4. and 7.2.2.1. through 7.2.2.4. are exempt from licensing in accordance with paragraph E.4.b. of DoD 8910-M (reference (h)).

7.2.2. Contingency Blood Reports. Blood program operations during contingencies or wartime shall be reported by ASBP activities using the following ASBP standardized U.S. Text Formats (USMTFs), as appropriate, in accordance with Joint Pub 6-04 (reference (i)).

7.2.2.1. The Blood Report and the Blood Shipment Report are two standard USMTF reports used to report contingency blood program operations.

7.2.2.2. The ASWBPL Situation Report is a standardized report used to summarize blood program shipment operations from the ASWBPL to the contingency area of operations.

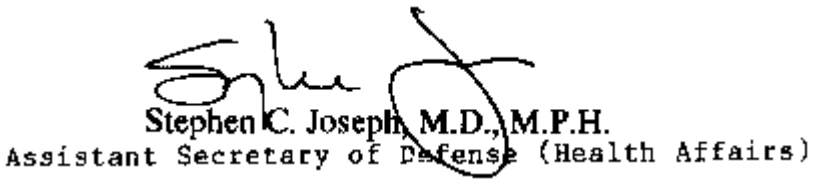
7.2.2.3. The ASBPO Situation Report is used to summarize the ASBP operations for the Chairman of the Joint Chiefs of Staff.

7.2.2.4. All Military Service BBs shall share infectious disease marker testing results, look back data, donor deferral lists, and other data, as required.

7.2.2.5. The Director, ASBPO, shall publish an annual DoD consolidation of the DD Form 2555 and a report on infectious disease marker testing and look back results from the blood donor population only.

8. EFFECTIVE DATE

This Instruction is effective immediately.



Stephen C. Joseph, M.D., M.P.H.
Assistant Secretary of Defense (Health Affairs)

Enclosures - 3

1. References
2. Definitions
3. ASBP-Mobilization Planning Factors

E1. ENCLOSURE 1

REFERENCES, continued

(e) Chairman of the Joint Chiefs of staff Memorandum of CJCSM 3122.03, "Joint Operation Planning System, Volume II, Planning Formats, and Guidance, ANNEX Q," current edition

(f) Joint Pub 4-02, "Doctrine for Health Service Support in Joint Operations," current edition

(g) Assistant Secretary of Defense for Health Affairs Memorandum, "Revised HIV testing and Look Back Guidelines for Homologous Blood Donations," July 22, 1993

(h) DoD 8910.1-M, "DoD Procedures for Management of Information Requirements," November 28, 1986.

(i) Joint Pub 6-04, "U.S. Message Text Format (USMTF)," current edition

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. American Association of Blood Banks (AABB). A civilian blood banking association that establishes policies and standards for BBs in the United States. The AABB also publishes the Standards for Blood banks and Transfusion Services," the "Technical Manual," and the "Accreditation Manual." Those publications have been adopted for peacetime, contingency, and wartime use by the Military Services as official publications.

E2.1.2. Armed Services Blood Program (ASBP). The combined military blood programs of the ASBPO, the individual Services and the Unified Combatant Commands in an integrated BPs support system for peacetime, contingency, and war.

E2.1.3. Armed Services Blood Program Office (ASBPO). A tri-Service-staffed, joint field operating Agency, with the Army as the DoD Executive Agent, responsible for coordination of the ASBP. That includes ensuring implementation of blood program policies established by the ASD(HA). It also includes standardization of policies, procedures, and equipment. The ASBPO is overall DoD manager for blood and BPs (class VIIIB), for the Chairman of the Joint Chiefs of Staff, during military contingencies and, when directed by appropriate governmental authorities, for civilian relief efforts.

E2.1.4. Armed Services Whole Blood Processing Laboratory (ASWBPL). A tri-Service-staffed organization, with the Air Force as the DoD Executive Agent, responsible for central receipt and confirmation of BPs from CONUS BBs, and shipment of those products to designated Unified Combatant Command BTCs and/or TBTCs.

E2.1.5. Blood Donor Center (BDC). Component-staffed; responsible for collection and processing of BPs. May be collocated with a BB in a MTF. In a Unified Combatant Command, a BDC may serve as a BSU. A BDC must meet the regulatory requirements for shipping blood (i.e., FDA license).

E2.1.6. Blood Products (BPs). A generic name for blood and blood components, (e.g., red blood cells (RBCs) (liquid and/or frozen), fresh frozen plasma, and platelet concentrates.)

E2.1.7. Blood Supply Unit (BSU). A Component-staffed unit responsible for the receipt and storage of BPs (liquid and/or frozen) from BTCs and/or TBTCs or BPDs, and the issue of those products to MTFs in an assigned geographic area, as directed by an AJBPO. A "BSU" may be any type unit or facility designated by a DoD Component.

E2.1.8. Blood Transshipment Center (BTC). An Air Force-staffed unit responsible for receiving BPs from an ASWBPL, BPD or another BTC and/or TBTC, reicing and/or storing those products, and issuing the products to BSUs or MTFs, in accordance with direction from the AJBPO.

E2.1.9. BP Depot (BPD). Component-staffed; responsible for strategic storage of frozen BPs in a Unified Combatant Command. Frozen BPs are provided to each Unified Command component based on JBPO instructions.

E2.1.10. BP Planning Factors. Factors used in computing mobilization requirements for BPs, (i.e., RBCs, fresh frozen plasma, and platelet concentrates).

E2.1.11. Food and Drug Administration (FDA). The Division of Blood and BPs in the CBER of the FDA that establishes blood banking regulations and requirements for use by BBs involved in inter-State commerce and grants licenses to BBs complying with those standards. The Military Departments voluntarily comply with those standards, and each Service Surgeon General holds a license for the respective Service's BBs.

E2.1.12. Joint Blood Program Office (JBPO). A tri-Service-staffed office responsible for overall joint BP management in a Unified Combatant Command theater of operations.

E2.1.13. Medical Treatment Facility (MTF). Any element or unit in which patients are treated, including Naval vessels.

E2.1.14. Red Blood Cells (RBCs). Cellular and oxygen-carrying elements separated from whole blood by removal of plasma. If drawn in the anticoagulant Citrate Phosphate dextrose Adenine-1, red blood cells must be transfused within 35 days of the date the blood is drawn. If frozen within 3 to 6 days of being drawn, they can be stored for up to 10 years under FDA license, and up to 21 years for use in military contingencies. Those units not transfused within 35 days of collection may be biochemically rejuvenated, frozen, and stored for the same time period described, above, for RBCs frozen within 3 to 6 days of collection. If RBCs are collected into

certain FDA-licensed additive solutions, they may be transfused within 42 days from collection.

E2.1.15. Service Blood Program Office (SBPO). A Service-staffed office responsible for coordination and management of that Service's blood program.

E2.1.16. Transportable Blood Transhipment Center (TBTC). A BTC that can be transported to other theater locations, as required to include bare base locations or locations with minimal infrastructure.

E3. ENCLOSURE 3

ASBP - MOBILIZATION PLANNING FACTORS

This enclosure prescribes the standard terminology and planning factors for use in computing mobilization requirements for blood and BPs needed for the treatment of conventional warfare casualties.

E3.1. Definitions

E3.1.1. Casualty. Includes all initial admissions for nonbattle injury plus wounded in action.

E3.1.2. Units of Measure. Each of the following individual products represents one unit of blood and blood products:

E3.1.2.1. Liquid Red Blood Cells; approximately 250 milli-Liters (mL).

E3.1.2.2. Deglycerolized RBCs; approximately 200 mL.

E3.1.2.3. Fresh frozen plasma; approximately 220 mL.

E3.1.2.4. Platelets (random donor); approximately 60 mL. (greater than 5.5×10^{10} platelets per unit)

E3.1.2.5. Platelet concentrates (pooled or apheresed); approximately 300mL.(greater than 3×10^{11} platelets/unit)

E3.2. Theater-Wide Blood Planning Factors

E3.2.1. RBCs; 4 units for each initial admission of WIA and NBI.

E3.2.2. Fresh frozen plasma; 0.08 units for each initial admission of WIA and NBI.

E3.2.3. Platelet concentrates; 0.04 units for each initial admission of WIA and NBI.

E3.2.4. The blood planning factors, which are historically founded, are resident in

the Medical Planning Module (MPM) by the Joint Data Systems Support Center, in the Logistics External Processor - Medical (LPXMED), and in the Medical Planning and Execution System (MEPES). Those planning systems can be utilized by the respective Unified Combatant Command's medical planners to generate daily BP requirements for the theater. The doctrine noted in Joint Pub 4-02 (reference (f)) requires deliberate planning to maintain 5 days of supply of blood and BPs (class VIIIB) in the theater of operations at all times.

E3.3. The Heads of the DoD Components

They shall apply current casualty rates to forces at risk for each operational plan. Those numbers shall be used with the appropriate planning factors in subsections E3.2.1. through E3.2.4., above, to determine the BP requirements, by 10-day periods, and incorporated in the respective OPLANS, as appropriate.

E3.4. Procedures

The BP requirements calculations are performed utilizing the available automated tools. Current tools include the JOPES MPM, MEPES, and the LPXMED. Those tools multiply the predefined planning factors times the population at risk to determine the requirements for each time period. Manual calculations utilize the same approach and are most appropriate for time-sensitive planning calculations used during execution periods or for a joint-task force requirement.